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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,129	08/24/2001	Rakesh Anand	P-280348	9676

7590 10/03/2002

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EXAMINER	
HASHEMI, SHAR S	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 10/03/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/857,129	Applicant(s) ANAND ET AL.	
	Examiner Shar Hashemi	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-12* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The application contains the following groups:

Group 1, claims 1-3, drawn to method of diagnosis of single nucleotide polymorphism.

Group 2, claims 4-5, drawn to a method of prognosis of Factor X-mediated disease.

Group 3, claims 10-11, drawn to a method of treating Factor X-mediated disease.

Group 4, claim 12, drawn to a computer readable medium.

Group 5, claim 6-9, drawn to nucleic acid with a T at position 41 in Exon 5 of Factor X gene.

Group 6, claim 6-9, drawn to nucleic acid with a T at position 57 in Exon 7 of Factor X gene.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. According to the guidelines in Section (f)(i)(B)(1) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush group have a common structure. Although chemical compounds of Groups 1-6 share a common structure of being composed of nucleotide bases, the compounds are not regarded as being of similar nature because the shared common structure is not a contribution over the prior art. The "special technical feature" of Groups 1-6 is a core common structure that is derived from the sequence of the parent Factor X gene which is shown by Cargill et al. (Nature Genetics,

22, 231-239, 1999) to lack novelty or inventive step of detecting single nucleotide polymorphism in human Factor X at exon 5 position 41 and exon 7 position 57 and does not make a contribution over the prior art.

According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(A) of Annex B of PCT Administrative Instructions, all alternatives of a Markush Group must have a common property or activity. Group 1 to 3 is drawn to methods involving active steps whereas Groups 5 & 6 are drawn to a product composed of nucleotides. Moreover, Group 4 is drawn to computer readable medium such as a magnetic disk.

According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(A) of Annex B of PCT Administrative Instructions, all alternatives of a Markush Group must have a common property or activity. Group 1 is drawn to a method of diagnosis or screening, Group 2 is drawn to method of predictive response to therapeutics and Group 3 is drawn to a method of treatment using antagonistic drug.

According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(A) of Annex B of PCT Administrative Instructions, all alternatives of a Markush Group must have a common property or activity. Although the chemical compounds of Groups 5 & 6 share a common structure of being composed of nucleotide bases, the compounds are not regarded as being of similar nature because all the alternatives do not share a common property or activity. The nucleic acid in Group 5 contains a T residue at position 41 in Exon 5 whereas the nucleic acid in Group 6 contains a T residue at position 57 in Exon 7 of Factor X gene. Therefore, the nucleotide change in Group 5 could function as a frameshift mutation while the nucleotide change in Group 6 could function as a missense mutation.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

CONCLUSION

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shar Hashemi whose telephone number is (703) 305-4840 and whose e-mail address is shar.hashemi@uspto.gov. However, the Office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can be best reached on weekdays from 7:00 a.m. to 3:30 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Sharon Thornton for Art Unit 1637 whose telephone number is (703)-305-3001.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-1235 and Before Final FAX (703) 872-9306 or After Final FAX (703) 308-9307.

September 26, 2002

JEFFREY SIEW
PRIMARY EXAMINER
10/1/02